Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 5656-34

I hereby certify that this correspondence is being transmitted electronically to the U.S. Patent and Trademark Office

on March 26, 2007

Signature Carey Gregory

Typed or printed name Carey Gregory

Application Number	Filed
10/727,123	12/02/2003

First Named Inventor: Raymond E. Ideker

Art Unit	Examiner
3766	Eric D. Bertram

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 48,441
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Laura M. Kelley
Typed or printed name

919-854-1400
Telephone number

March 26, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Attorney Docket No. 5656-34 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Raymond E. Ideker et al.
Application Serial No.: 10/727,123
Filed: December 2, 2003
Group Art Unit: 3766
Confirmation No. 4773
Examiner: Eric D. Betram
For: **METHODS, SYSTEMS AND COMPUTER PROGRAM PRODUCTS TO INHIBIT VENTRICULAR FIBRILLATION DURING CARDIOPULMONARY RESUSCITATION**

Date: March 26, 2007

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REASONS IN SUPPORT OF APPLICANTS' PRE-APPEAL BRIEF REQUEST FOR REVIEW

This document is submitted in support of the Pre-Appeal Brief Request For Review filed concurrently with a Notice of Appeal for the above-referenced patent application. No amendments are being filed with this Request.

If any extension of time for the accompanying response or submission is required, Applicants request that this be considered a petition therefor. The Commissioner is hereby authorized to charge any additional fee, which may be required, or credit any refund, to Deposit Account No. 50-0220.

REMARKS

Applicants hereby request a Pre-Appeal Brief Review (hereinafter "Request") of Claims 26-28, 41-43, and 52, which stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,772,613 to Gelfand et al. ("Gelfand") in view of "Commotio cortis: sudden death due to chest wall impact in sports" by Link ("Link") and of Claims 31-33, 44, 45, 52 and 54-57, which stand finally rejected under 35 U.S.C. § 103(a) is being unpatentable over Gelfand and Link in further review of U.S. Patent No. 6,390,996 to Halperin ("Halperin"). Applicants respectfully submit that all of the claim recitations of the independent claims are not described or suggested, so that one or more elements needed for a *prima facie* rejection under 35 USC §103(a) are not present. Therefore, Applicants

respectfully request review of the present application by an appeal conference prior to filing of an Appeal Brief. In the interest of brevity, and without waiving the right to argue the additional grounds should this Request be denied, Applicants will point out the omission of one or more essential elements needed for a *prima facie* rejection in the Office Action mailed November 24, 2006 (the "Action") and the Advisory Action mailed March 8, 2007 (the "Advisory Action").

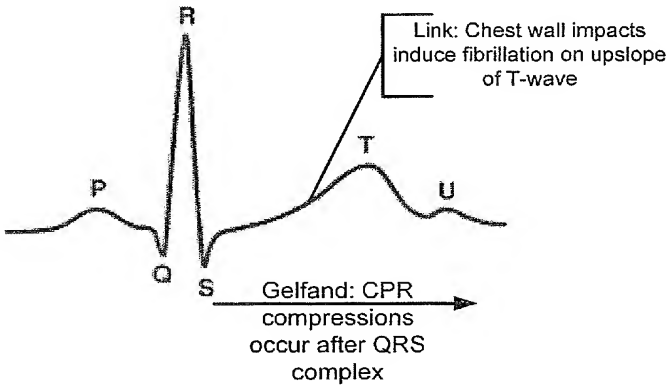
Claim 26 recites a method for performing chest compression during cardiopulmonary resuscitation (CPR), including:

> sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity of a heart in a subject undergoing CPR;
> identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject based on the sensed parameter; and
> compressing the heart of the subject during a non-vulnerable portion of the intrinsic cardiac cycle based on the identifying step thereby inhibiting reinduction of fibrillation and/or improving cardiac function.

The Action concedes that Gelfand does not disclose identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject and compressing the heart of the subject during a non-vulnerable portion based on the identifying step; however, the Action takes the position that Link discloses that chest impacts on the upslope of the T wave results in ventricular fibrillation. The Action concludes that it would have been obvious to combine Gelfand with Link to time the compressions to avoid the vulnerable "up-slope" T-wave portion of the cardiac cycle.

Applicants respectfully disagree. Notably, Gelfand proposes timing compressions so that they apparently coincide with the portion of the cardiac cycle (the upslope of the T wave) in Link that resulted in ventricular fibrillation. As such, Gelfand teaches away from avoiding chest wall compressions during this portion of the cardiac cycle. In addition, there is no motivation to combine the teaching of Link, which describes inducing ventricular fibrillation with chest wall impacts in healthy individuals, and the cardiopulmonary resuscitation (CPR) system of Gelfand.

In particular, Gelfand discusses in column 9, lines 5-10, that the timing of the inflation phase of the vest (corresponding to a compression of the heart) may be at "a predetermined time following the QRS complex wave of the ECG signal." In contrast, Link hypothesizes that ventricular fibrillation in healthy individuals may be caused by a chest wall impact during a vulnerable period of the cardiac cycle, *i.e.*, the upslope of the T-wave. Link, page 1, paragraph 2. As illustrated in the schematic diagram of an ECG below, Gelfand teaches test compressions that coincide with the chest wall impacts which caused fibrillation (the upslope of the T-wave) in Link.



Applicants note that the Advisory Action stated that portions of the ST segment occurs after the QRS complex, but before the upslope of the T-wave. *See* the Advisory Action, page 2. Applicants further note that the downslope of the T-wave and the U-wave also occur after the QRS complex. It may, therefore, be possible to apply a compression in the time period after the QRS complex according to the teachings of Gelfand that does not coincide with the upslope of the T-wave as noted in the Advisory Action. However, as can be seen in the schematic ECG signal above, the time period following the QRS complex, which is identified in Gelfand for chest compressions, also clearly coincides with the upslope of the T-wave portion of the cardiac cycle. In contrast to the teachings of Gelfand, Link discusses that chest wall impacts can induce fibrillation when the impact occurs on the upslope of the T-wave. Applicants submit that Gelfand teaches away from **avoiding** CPR compressions on the upslope of the T-wave portion of the cardiac cycle because Gelfand specifically identifies

portions of the cardiac cycle including the upslope of the T-wave as a time period in which compressions should be applied.

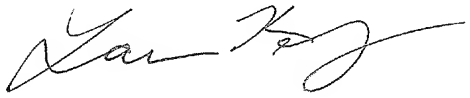
In addition, there is no motivation to combine Link and Gelfand. Link is concerned with sudden death resulting from chest wall blows in young, healthy people in sports such as hockey, lacrosse, softball and baseball. Link discusses that the victims of this condition have no known histories of heart disease or other chronic medical illness. Link, page 1, paragraphs 1-2. Link hypothesizes that ventricular fibrillation in healthy individuals may be caused by a chest wall impact during a vulnerable period of the cardiac cycle. Link, page 1, paragraph 2. In contrast, Gelfand proposes a cardiopulmonary resuscitation (CPR) system that is used on patients that are generally already experiencing ventricular fibrillation, or as the Advisory Action correctly notes, in individuals that have a beating, yet weakened heart. Gelfand, col. 1, lines 25-28 and col. 8, line 62 – col. 9, line 10.

Applicants submit that there is no teaching or suggestion in Gelfand or Link that that the findings of induced fibrillation in Link in healthy individuals should be applied to the application of CPR to sick patients experiencing ventricular fibrillation and/or a weakened heart as maintained in the Action and the Advisory Action. There is also no suggestion in the references that sick individuals would be just as a vulnerable or more vulnerable to the induction of ventricular fibrillation as maintained in the Advisory Action on page 3. Therefore, Applicants submit that there is no motivation to combine the teachings of Link, which involve inducing ventricular fibrillation in healthy individuals, with the CPR device of Gelfand, which is used on sick patients that may already be experiencing ventricular fibrillation. In summary, neither Gelfand nor Link teach or suggest 1) identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject based on the sensed parameter and/or 2) compressing the heart of the subject during a non-vulnerable portion of the intrinsic cardiac cycle based on the identifying step thereby inhibiting reinduction of fibrillation and/or improving cardiac function as recited in independent Claim 26. These features are also not taught or suggested by U.S. Patent No. 6,390,996 to Halperin ("Halperin") (discussed on pages 5-7 of the Action). The particular deficiencies of Halperin are in the Response submitted September 16, 2006.

Independent Claims 41, 42 and 49 include similar recitations to those emphasize with respect to independent Claim 26 for a system for performing chest compressions (Claims 41 and 42) and a computer program product for timing the delivery of chest compressions (Claim 49) and are also patentable over the cited art for at least the reasons discussed above. Claims 27-40, 43-48, 50-59 depend directly or indirectly from independent Claims 26, 41, 42 or 49 and are patentable at least per the patentability of the claims from which they depend.

For the reasons discussed above, Applicants submit that one or more elements needed for a *prima facie* rejection under 35 USC §103(a) are not present. Therefore, Applicant respectfully requests that the present application be reviewed and reversed by the appeal conference prior to the filing of an Appeal Brief.

Respectfully submitted,

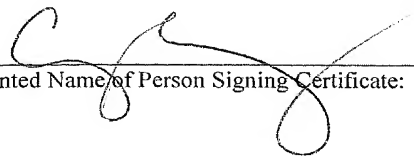


Laura M. Kelley
Registration No. 48,441

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on March 26, 2007.

Signature: 

Typed or Printed Name of Person Signing Certificate: Carey Gregory